Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)
	)
Sensible Medical Innovations	)
Request for Waiver of Part 15 of the	)
Commission's Rules Applicable	)
to Ultra-Wideband Devices	

SENSIBLE MEDICAL INNOVATIONS REQUEST FOR WAIVER

Inbal Ben-Tzvi
SENSIBLE MEDICAL INNOVATIONS LTD.
6 Meir Ariel Street
Netanya 4059300
Israel
POB 8702

/s/ Michele C. Farquhar
Michele C. Farquhar
Tom Peters
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, DC 20004
Phone: (202) 637-5663

Counsel to Sensible Medical Innovations

January 16, 2018

TABLE OF CONTENTS

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)
	)
Sensible Medical Innovations	)
Request for Waiver of Part 15 of the	)
Commission's Rules Applicable to Ultra-Wideband Devices	)

SENSIBLE MEDICAL INNOVATIONS REQUEST FOR WAIVER

Sensible Medical Innovations Ltd. ("Sensible"), through its counsel, hereby requests a limited waiver of the Federal Communications Commission's ("FCC" or the "Commission") Part 15 rules governing ultra-wideband ("UWB") medical imaging devices. Sensible intends to market a stepped-frequency UWB medical monitoring device that uses dielectric sensing to provide non-invasive monitoring of patients suffering from congestive heart failure (the "ReDS System"). Because the ReDS System operates at frequencies below 3.1 GHz, device certification requires a waiver of Section 15.513(a) of the Commission's rules. Certification for the ReDS System requires additional waivers of Sections 15.503(d) (the definition of "UWB transmitter"), 15.31(c) (measurement standards for swept frequency equipment), 15.521(d) (measurement procedures for radiated emission limits at band edges), and 15.525 (the federal coordination requirement).

The Commission has the authority to grant a waiver request when the purpose of the rule (*i.e.*, protecting against harmful interference) would not be frustrated and the granting of the waiver would be in the public interest. Given that the minimal risk of harmful interference is far outweighed by the important healthcare benefits from the ReDS System, there is good cause for the Commission to grant a limited waiver of its Part 15 rules.

I. OVERVIEW OF THE REDS SYSTEM AND HOW IT WOULD BENEFIT THE PUBLIC INTEREST

About 5.7 million adults in the United States suffer from congestive heart failure ("CHF").[1] One in nine deaths in 2013 included heart failure as a contributing cause.[2] About half of the people who develop heart failure die within five years of diagnosis.[3]

One of the key indicators when managing heart failure is pulmonary congestion, a potentially fatal condition. Pulmonary congestion is the most common cause of worsening heart failure leading to hospitalization, and readmission rates can be as high as 50% during the six months after a discharge.[4] Studies have shown that hospital readmissions for CHF could be reduced through monitoring and early detection.[5] Accurate monitoring of lung fluid volume can assist in guiding optimal treatment and prevent readmission after hospitalization.

The ReDS System is designed to improve the quality of managed care for patients with lung fluid management problems, including heart failure patients, whether in the home or in a healthcare facility. Providing accurate lung fluid measurements in a non-invasive and convenient way, the ReDS System can improve the care of heart failure patients and reduce readmission rates. For example, in one study, 74% of notifications from the ReDS System led to changes in treatment, 80% of these changes led to fluid reduction, and 87% of these patients'

---

[1] *Heart Failure Fact Sheet*, Center for Disease Control and Prevention (last updated June 16, 2016), http://bit.ly/2mQl9xv (citing Dariush Mozaffarian et al., *Heart Disease and Stroke Statistics—2016 Update*, 132 CIRCULATION e1-e323 (2015), http://bit.ly/2k2R1if) ("*Heart Failure Fact Sheet*").

[2] *Heart Disease and Stroke Statistics—2016 Update* at e5.

[3] *Heart Failure Fact Sheet*.

[4] Akshay S. Desai *et al.*, *Rehospitalization for Heart Failure – Predict or Prevent?*, 126 CIRCULATION 501 (2012), http://bit.ly/2zdlPSh.

[5] *See, e.g.*, W.T. Abraham *et al.*, *Wireless Pulmonary Artery Haemodynamic Monitoring in Chronic Heart Failure: A Randomised Controlled Trial*, 377 LANCET, 658-66 (2011), http://bit.ly/2zcmTpo (finding that an implantable pulmonary artery sensor reduced hospitalizations by 37% over 15 months and suggesting that a 58% reduction in 30-day readmissions).

readings returned to within the pre-defined threshold within a week.[6] In another study, the ReDS System was shown to have the potential to reduce CHF readmission rates.[7]

The ReDS System is a bedside monitor that provides measurements of a patient's lung fluid content. Two sensors are attached to the thorax: one anteriorly on the chest and the other posteriorly on the back, with the patient's lung positioned directly between the sensors. Each sensor consists of an antenna for transmitting and receiving the electromagnetic ("EM") waves transferred through the pulmonary tissue. The dielectric properties of the lung alter the transmitted EM wave, and these changes are measured by the ReDS System. The dielectric coefficient of a material is represented by a frequency-dependent complex number describing its interaction with EM energy (wave impedance), including the degrees of absorption, reflection and transmission of the energy. The dielectric coefficient of pulmonary tissue is determined by the dielectric coefficients of each of its components (*e.g.*, blood, lung parenchyma, and air) and their relative concentrations. Accordingly, the dielectric coefficient of a lung is very sensitive to the ratio between the volumes of air and water and, thus, this number is a direct indicator of fluid concentration.

The ReDS System consists of a vest connected to a bedside console.[8] The vest encases the two sensors and a pneumatic pressure attachment mechanism. The bedside console is an

---

[6] William Abraham *et al.*, *Evaluation of Reds-Guided Patient Management in Ambulatory Heart Failure Patients At-Risk for Rehospitalization*, 17 (Suppl. 1) EUR. J. HEART FAILURE 78-79 (2015).

[7] Offer Amir et al., *Evaluation of Remote Dielectric Sensing (ReDS) Technology-Guided Therapy for Decreasing Heart Failure Re-Hospitalizations*, 240 INT. J. OF CARDIOLOGY 279 (2017), http://bit.ly/2CRK4aM ("The ReDS non-invasive technology provides sensitive and actionable alerts that serve as an early detection system of decompensation with relatively low burden to patients and the health care system. Maintaining normal lung fluid content based on ReDS in these patients results in reductions of BNP levels and reduced hospitalizations compared to the pre- and post-study periods.").

[8] Future versions of the ReDS system may have form factors that do not resemble a vest.

enclosure housing the electronic modules, an embedded computer, and a touch-screen display. The device's software manages the operation of the device, as well as analysis of the measured signals and user interface functions. The sensors are shielded from all sides except for the body-attached side. The sensors are pressed against the thorax by the vest and the pneumatic mechanism. The pressing of the non-shielded side of the sensor against the thorax, together with the sensor impedance that is matched to the body, ensure that the radiation is well coupled to the body, which absorbs and attenuates it, making the possibility of any unwanted emissions extremely low.

The ReDS System is operated at the direction or under the supervision of a physician, whether it is used in patient's home or in a healthcare facility. A single lung fluid content measurement lasts about 90 seconds. The device is expected to be used several times per day (once a day at home and up to 20 times per day at a healthcare facility). Transmission is halted if the device is removed. To allow the device to be operated by the patient rather than a healthcare professional, the ReDS system ensures proper positioning of the sensors prior to initiating signal transmission.

Finally, the ReDS System uses stepped-frequency modulation and operates in the frequency range of 1005-1709 MHz, with a dwell time of four milliseconds, and a duty cycle of 2.1-5.2% (per frequency).

II. WAIVERS REQUESTED FOR THE REDS SYSTEM

The Commission is authorized to grant requests for a waiver under Section 1.3 of the Commission's rules if the petitioner demonstrates good cause for such action.[9] Good cause may

[9] 47 C.F.R. § 1.3. *See also* 47 C.F.R. § 1.925(b)(3)(i) ("The Commission may grant a request for waiver if it is shown that: [t]he underlying purpose of the rule(s) would not be served or would be frustrated by application to the instant case, and that a grant of the requested waiver would be in the public interest . . . .").

be found "where particular facts would make strict compliance inconsistent with the public interest."[10] "To make this public interest determination, the waiver cannot undermine the purpose of the rule, and there must be a stronger public interest benefit in granting the waiver than in applying the rule."[11]

Sensible seeks certification for the ReDS System as a UWB transmitter under Part 15 of the Commission's rules. The UWB technical and operational standards were adopted to ensure that UWB medical imaging devices operate on a non-interfering basis with other services.[12] As discussed below, operation of the ReDS System will not cause harmful interference to incumbent services, and thus a grant of the requested waivers would not undermine the purpose of the Part 15 rules. And because the ReDS System provides significant public interest benefits through its non-invasive imaging technology that can assist in managing care for patients suffering from congestive heart failure,[13] the grant of the requested waivers will yield far greater public interest benefits than would applying the rules.

A. Request for Waiver of Section 15.503(d)'s Definition of "Ultra-Wideband Transmitter"

Section 15.503(d)[14] defines a UWB transmitter as a device that "at any point in time" has a fractional bandwidth equal to or greater than 0.20 or has a UWB bandwidth equal to or greater

[10] *ICO Global Communications (Holdings) Limited v. FCC,* 428 F.3d 264, 269 (D.C. Cir. 2005) (citing *Northeast Cellular Telephone Co. v. FCC,* 897 F.2d 1164, 1166 (D.C. Cir. 1990)).

[11] *Kyma Medical Technologies Ltd. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices*, Order, 31 FCC Rcd 9705 ¶ 5 (2016) (citing *WAIT Radio v. FCC,* 418 F.2d 1153, 1157 (D.C. Cir. 1969)) ("*Kyma Waiver Order*").

[12] *Revision of Part 15 of the Commission's Rules Regarding Ultra-Wideband Transmission Systems*, First Report and Order, 17 FCC Rcd 7435 ¶¶ 4-5 (2002) ("*UWB First Report and Order*").

[13] *See* Section I at 2.

[14] 47 C.F.R. § 15.503(d).

than 500 megahertz. Fractional bandwidth is defined by the equation $2(f_H - f_L)/ (f_H + f_L)$.[15] The ReDS System steps a continuous wave signal through the 1005-1709 MHz range, resulting in a fractional bandwidth of less than .2 and individual transmissions of less than 500 megahertz, and thus the ReDS System requires a waiver of Section 15.503(d).

In evaluating a petition for waiver of Section 15.503(d) for a UWB ground penetration radar system ("GPR") that used stepped-frequency modulation, the Commission considered whether the system was "functionally equivalent to UWB GPR devices and that the risk of interference from the [petitioner's device] will be no greater than from UWB GPR devices."[16]

The risk of interference due to operation of a ReDS System is no greater than other UWB medical imaging devices. The ReDS System is functionally equivalent (or nearly equivalent) to another FCC-certified medical imaging device (the "Kyma uCor") that uses stepped-frequency modulation and received a waiver of Section 15.503(d).[17] In granting the waiver request, the Commission observed that "[t]he UWB imaging rules were designed to accommodate devices that emit impulsive or transient-like signals that are spread across a very wide bandwidth to produce an image within the body."[18]

Unlike the types of devices that the Part 15 UWB rules were intended to address, but similar to the Kyma uCor device that received a waiver of Section 15.503(d), the ReDS System uses stepped-frequency modulation to gather all the data needed in a single pass. While one frequency used for one hop sits at the very edge of the GPS band (at 1164.0625 MHz), this device will be used primarily indoors and essentially steps around the GPS band—not into it (the

[15] 47 C.F.R. § 15.503(c).
[16] *Curtiss-Wright Controls Inc. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices*, Order, 27 FCC Rcd 234 ¶ 14 (2012).
[17] *See Kyma Waiver Order* ¶ 8.
[18] *Id*.

next frequency used is 1243.0625 MHz). And since the device operates with a low daily duty cycle (2% daily operation duty cycle, and less than 0.1% actual transmission daily duty cycle at any given frequency) and a dwell time of 4 milliseconds, there little to no risk of interference. Thus, the purpose of Section 15.503(d) would not be undermined. Given the public interest benefits of the ReDS System, waiver of Section 15.503(d) is appropriate.

B. Request for Waiver to Operate Outside the Frequency Range Prescribed in Section 15.513(a)

Section 15.513(a)[19] requires Part 15 UWB medical imaging devices to operate within the frequency range of 3.1-10.6 GHz. This range was adopted by the Commission in its 2002 *UWB First Report and Order* as a way to strike a balance between protecting existing spectrum users from potential interference and promoting new UWB technologies.[20]

EM waves of the ReDS System propagate through the thorax of the patient to achieve an accurate, sensitive, and pre-symptomatic lung fluid content measurement. To achieve an accurate measurement, these waves must travel a long distance through the lung, from one side to the other. Frequencies in the range of 3.1-10.6 GHz cannot propagate through the thorax due to the extremely high attenuation and therefore cannot be utilized for lung fluid measurements. For comparison, the ReDS System's frequency range, 1005-1709 MHz, can suffer as much as 100 dB attenuation. A waiver of Section 15.513(a) is appropriate because accurate lung fluid detection requires frequencies that can propagate through the body, which is not technologically possible with frequencies between 3.1-10.6 GHz, and because there is little to no risk of harmful interference.

[19] 47 C.F.R. § 15.513(a).
[20] *UWB First Report and Order* ¶ 18.

Moreover, any potential risk of harmful interference by the ReDS System can be balanced by operational and technical restrictions. As the Commission noted in its Order granting a waiver of Section 15.513(a) for the Kyma uCor,

> the interference potential of UWB devices to authorized services can be controlled by several factors. Limits on the average and peak emission levels produced by the devices are one method of controlling potential interference and limiting the applications for which the devices may be employed and the manner in which the devices may be operated is another.[21]

The Commission conditioned the waiver on the requirements that the Kyma uCor operate within the stated frequency range claimed by Kyma and that the uCor would only operate when in close proximity or in contact with the human body for the purposes of seeing inside the body to detect objects or fluid levels, with the device's energy directed into the body cavity.[22] These same conditions are also capable of being met during normal operation of the ReDS System (which uses a body-coupled, shielded EM transducer), and thus the purpose of Section 15.513(a) would not be frustrated if a waiver were granted. When considered in light of healthcare benefits that the ReDS System promises to yield, the public interest would greatly benefit if a waiver is granted and, accordingly, a waiver of Section 15.513(a) is appropriate.

---

[21] *Kyma Waiver Order* ¶ 15 (citing *Revision of Part 15 of the Commission's Rules Regarding Ultra-Wideband Transmission Systems,* Second Report and Order and Second Memorandum Opinion and Order, 19 FCC Rcd 24558, 24564 (2004)); *see also UltraVision Security Systems, Inc. Request for Interpretation and Waiver of Section 15.511(a) & (b) of the Commission's Rules for Ultra-Wideband Devices*, Order, 23 FCC Rcd 17632 (2008) (granting a petition for waiver of 47 C.F.R. § 15.511, allowing for the operation of a GPR system in the 80-600 MHz frequency range).

[22] *Kyma Waiver Order* ¶ 16.

C. Request for Waiver of the Measurement Procedures Defined in Sections 15.31(c) and 15.521(d)

Section 15.31(c)[23] defines the measurement standards for unlicensed devices to demonstrate compliance with applicable emissions limits and requires that swept frequency equipment measurements be made with the frequency sweep stopped. Section 15.521(d)[24] defines measurement procedures to demonstrate that operation of a UWB device is within applicable limits. For radiated emissions levels above 960 MHz, this rule requires that those levels be based on a root-mean-square average measurement with a one millisecond or less averaging time. Sensible requests a waiver of both of these requirements to allow for measurements to be done with frequency stepping active and a 50 millisecond averaging time.

The Commission has granted waivers of these rules for other devices that employ frequency hopping or stepped-frequency modulation techniques by allowing measurement to take place under normal transmission mode, which also allows a measurement to account for the averaging time during which the UWB emitter is not transmitting.[25]

> In reaching its decisions, the Commission recognized that the interference aspects of a transmitter employing frequency hopping, stepped frequency modulation, or gating are quite similar, as viewed by a receiver, in that transmitters using these burst formats appear to the receiver to emit for a short period of time followed by a quiet period. The Commission concluded that any requirement to stop the frequency hopping, band sequencing, or system gating serves only to add another unnecessary level of conservatism to already stringent UWB standards.[26]

---

[23] 47 C.F.R. § 15.31(c).

[24] 47 C.F.R. § 15.521(d).

[25] *See Kyma Waiver Order* ¶¶ 10-12; *see also Petition for Waiver of the Part 15 UWB Regulations Filed by the Multi-band OFDM Alliance Special Interest Group,* Order, 20 FCC Rcd 5528 (2005) ("*MBOA-SIG Waiver*").

[26] *Kyma Waiver Order* ¶ 11 (citing *MBOA-SIG Waiver* ¶ 13).

For the same reasons that the Commission granted past waivers of Sections 15.31(c) and 15.521(d) for the Kyma uCor and other UWB imaging devices, the ReDS System also meets the conditions required for a waiver to be granted.

The ReDS System's EM signal sweeps through 16 frequencies. At each frequency, a four millisecond dwell time, a one millisecond calibration time, and a 300-400 microsecond synthesizer stabilization time result in a cycle time of about 85 milliseconds. The ReDS System, like many frequency hopping devices, spreads power over different frequencies, creating a low average power. A high signal-to-noise ratio ("SNR") is required to achieve high lung fluid measurement sensitivity while coping with approximately 100 dB body attenuation. The need for a high SNR dictated a design that relies on a synthesizer with a considerable stabilization time. The un-utilized stabilization time requires a dwell time of four milliseconds to preserve reasonable efficiency.

The average power limit defined for UWB is extremely low, specifically in the frequency band utilized by the ReDS System (1- 1.8 GHz).[27] In order to achieve the required accuracy, stepping through multiple frequencies covering the wide range indicated is necessary, resulting in intermittent transmission at each frequency. The ReDS System's peak power is about 47 dBμV/m at three meters (measured with a saline phantom). Given the dwell time of four milliseconds, a measurement procedure performed with an averaging time of one millisecond as required by Section 15.521(d) will result in an average power which is equal to the peak power measurement (about 47 dBμV/m at three meters). While the ReDS System peak power is well within peak limits, this average power would exceed the required level limits by about 17 dB (the most stringent requirement is the frequency band below 1610 MHz in which the limit is 29.9

[27] Use of this band is needed to penetrate the body from side to side.

dBμV/m at three meters[28]). Therefore, a power reduction of nearly 20 dB would be required to meet the one millisecond average power limits, and this would reduce SNR well below the levels needed for reasonable estimation accuracy.[29] As a result, a peak to average ratio of about 20 dB is needed. Since the ReDS System requires a dwell time of four milliseconds, an averaging time of 50 milliseconds would provide the needed peak to average ratio.

Since the low-power transmissions of the ReDS System would only occur intermittently (1-20 times per day, depending on the managed care plan prescribed), would only occur for brief periods of time (up to 90 seconds duration per scan), would primarily occur in indoor locations, and would be directed towards a patient's body cavity, there is very little risk of harmful interference to other services. In light of the public interest benefits the device would provide, waiver of Sections 15.31(c) and 15.521(d) is appropriate.

D. Request for Waiver of the Coordination Requirements of Section 15.525

Section 15.525[30] requires that UWB imaging systems coordinate with federal users through the FCC before the equipment may be used. The Commission adopted the coordination requirement for imaging devices in response to the National Telecommunications and Information Administration's request to protect potentially affected federal government operators providing safety-of-life services.[31]

In the *Kyma Waiver Order*, the Commission granted a waiver of Section 15.525, acknowledging that the primary purpose of the rule was to assist with keeping track of ground

[28] For the band 960-1610 MHz, Section 15.513(d) requires the EIRP to be equal to or less than −65.3 dBm. This has been converted to field strength at three meters using the formula shown in Section 15.521(g), E(dBμV/m) = P(dBm EIRP) + 95.2.
[29] This is especially true for congested patients, since congestion introduces extreme signal attenuation.
[30] 47 C.F.R. § 15.525.
[31] *UWB First Report and Order* ¶ 19.

penetration radars that would potentially be used for extended periods in outdoor locations and that "coordinating the deployment of mobile body worn devices would not be practical or provide information that would be useful to prevent harmful interference."[32] The characteristics of the device under consideration in the *Kyma Waiver Order* are also present here—the ReDS System is a body-worn device that will operate intermittently indoors (principally, in a healthcare facility or patient's home). There is little risk of harmful interference, and the purpose of this rule would not be frustrated by grant of a waiver. Given the public interest benefits of the ReDS System, a waiver of Section 15.525 is appropriate.

III. CONCLUSION

The ReDS System furthers an important public interest by helping to manage care for patients suffering from congestive heart failure. By enabling physicians and patients to monitor pulmonary congestion, the ReDS System can improve patient health and reduce hospitalization rates among CHF patients by providing accurate, up-to-date information in a non-invasive fashion. Since there is little to no risk of harmful interference caused by the ReDS System, the requested waivers are appropriate under the Commission's standards and precedents, and the Commission should grant these waivers as expeditiously as possible.

Respectfully submitted,

/s/ Michele C. Farquhar
Michele C. Farquhar
Tom Peters
HOGAN LOVELLS US LLP
555 Thirteenth Street, N.W.
Washington, DC 20004
Phone: (202) 637-5663

Counsel to Sensible Medical Innovations

Inbal Ben-Tzvi
SENSIBLE MEDICAL INNOVATIONS LTD.
6 Meir Ariel Street
Netanya 4059300
Israel
POB 8702

January 16, 2018

[32] *Kyma Waiver Order* ¶ 19.